Serial No. 09/766,399
Group Art Unit: 1634

REMARKS

Reconsideration of the present application is respectfully requested. The Examiner is requested to enter the amendments submitted, as Applicants believe that these amendments put the claims in condition for allowance. Applicants respectfully reserve the right to file divisional applications or take other such appropriate measures to protect the subject matter in the cancelled claims.

Status of the Claims

Claims 1-16 remain in this application. Claims 1, 17 and 18 have been cancelled without prejudice. Claims 2, 7, 8, 12 and 16 have been amended.

Support for the amended claims is found throughout the specification, most notably pages 4-14, and 26-34. No new matter has been added by way of amendment to the claims.

Attached hereto is a marked-up version of the changes made by the current amendment. The attached page is captioned **"Version with markings to show changes made".**

Claim Objections

The Examiner objects to claims 2-6 and 8-15, because they refer to the drawings in section (i) of the claims. From MPEP 2173(s) the Examiner quotes " Where possible claims are to be complete in themselves. Incorporation by reference to a specific figure or table is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience". The Examiner states that the drawings contain sequences which can be concisely identified by sequence identifiers.

Applicants respectfully submit, the claims as filed did not refer to figures, but to SEQ ID NOS. However, in an effort to expedite prosecution and to better define the

claimed invention, Applicants have amended claims 2, 8 and 12 to incorporate the SEQ ID NO of each promoter element where appropriate.

Rejections under 35 USC § 112 second paragraph

The Examiner has rejected claims 1-6 and 8-16 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Examiner states " these claims are indefinite because it is not clear how the information in parentheses is meant to be limiting to the claim", and indicates that it is not clear if the element must comprise or consist of the sequence identifier appearing in parentheses, or if it is merely an example of one such element encompassed by the claims.

Applicants have noted the Examiner's point regarding the ambiguity detected in the claims as originally submitted. Applicants would like to thank the Examiner for her suggestion regarding rephrasing. The claims containing sequence identifiers have been rewritten to more particularly point out and distinctly claim the subject matter.

Rejections under U.S.C. 112 § first paragraph

The Examiner has rejected claims 1-16 under U.S.C. §112, first paragraph, because the specification does not reasonably provide enablement for any SMPERs that are identified merely by the combination of elements contained therein, or those modified from the recited sequence identifiers. The Examiner further states that the rejection is particularly applied to the rejected claims to address claims which require the elements recited in claim 1(c) in any order, variants of SEQ ID NO: 65, and sequences that hybridize to 1(c) or 2(c). Also, the Examiner states that the specification does not provide any guidance as to how the elements can be rearranged from the order of SEQ ID NO: 65 and still result in a functional promoter, and that the claims to sequences that hybridize to, or are variants of, the recited promoters and elements require that the specification provides examples of a modified element which would still retain the ability to promote transcription.

Serial No. 09/766,399
Group Art Unit: 1634

Applicants respectfully submit that the specification is not required to disclose all possible permutations defined by "a plant promoter comprising at least one synthetic multimeric promoter element region having a nucleotide sequence selected from the group consisting of a nucleotide sequence comprising five DRE1, three ABRE1, two AS-1, and five GT-2 promoter elements", or "a nucleotide sequence comprising promoter elements GT-2, ABRE1, ABRE1, GT-2, As-1 7, GT-2, GT-2, DRE1, GT-2, DRE1, DRE1, As-1, DRE1, DRE1, and ABRE1, sequentially (SEQ ID NO.: 65) ". The specification is required to provide sufficient disclosure and enablement so that one skilled in the art could make the embodiments encompassed by claim 1(c) and claim 2(c):

> The function of [the] description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; to comply with the description requirement, it is not necessary that the application describe the claimed invention *in ipsis verbis*; all that is required is that it reasonably convey to persons skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed by him. *In re Edwards* 568 F. 2d at 1351-52, 196 U.S.P.Q. at 467

Claims 2, 8 and 12 have been amended for clarity, and now include full length GAP sequence identity percentage limitations, as found in the specification, pages 16-17. The present application provides sufficient information and guidance to enable one of skill in the art to make and use a polynucleotide with at least about 90% sequence identity as determined by the GAP algorithm under default parameters, across the full length of the claimed sequence. The specification provides a working example of the isolation of SEQ ID NO: 65 on page 28, lines14-28.

The specification describes variants and identification of sequences resulting from site-directed mutagenesis (page 12) that would encompass sequences with at least about 90% sequence identity to SEQ ID NO: 65. The specification provides information suitable for isolating the sequences, their variants and the mutations, methods for identifying the variants and mutations (page 12, lines 12-20). Methods for inducing mutations and variants are well known to those of skill in the art such as the

use of degenerate PCR cycles (Gould et al. Proc Natl. Acad. Sci. USA, 86:1934-1938 (1989)) and oligonucleotide muatgenesis (F.M. Ausubel et al., Eds., Current Protocols, a joint venture between Greene Publishing Associates, Inc. and John Wiley & Sons, Inc. (1995)).

The Examiner asserts there is no way to predict which promoters would be functional, and therefore further asserts that the construction and screening involved would cause undue experimentation. The Applicant respectfully traverses the assertion.

> It is well established that only "when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required" *Genentech, Inc. v. NovoNordisk, 108 F3d 1361, 42 USPQ2d 1001 (Fed. Cir. 1997).*

The specification provides ample disclosure of starting material such as appropriate tissues (see Example 1, pages 26-28 of the specification) and conditions (pages 28-29). By using the disclosed materials, examples, and the established protocols cited in the specification, one of skill in the art would readily be able to synthesize any number of sequences as claimed in Claims 1(c) and 2(c).

The Examiner concludes that "in light of the broad scope of the claims, the high level of unpredictability in the promoter art, the lack of examples and direction provided in the specification, and the high level of experimentation necessary to practice the claimed invention, it is concluded that undue experimentation is necessary to practice the claimed invention commensurate in scope with the instant claims."

> Enablement is lacking in cases where the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation. The question of experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is the amount of experimentation must not be unduly extensive. *PPG Inc. V. Guardian Industries Corp.* (37 USPQ 1218, 1623, (Fed. Cir. 1996))

The present specification provides reasonable guidance with respect to the direction in which the experimentation should proceed by providing sequences, methods, citations and examples sufficient to practice the scope of the claims. While the methods require selection of promoter exhibiting the desired activity, the selection is routine and would not require undue experimentation. No matter how much detail is provided, one will have to select for the desired promoter function.

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed. *Ex parte Jackson*, 217 USPQ 804, 807 (1982 PTOBA).

Applicants have cancelled Claim 1 without prejudice. In an effort to expedite prosecution, claims 2, 8 and 12 have been amended to cancel without prejudice reference to variants of SEQ ID NOS.: 66-72. In addition, Claims 2, 8 and 12 have been amended to include specific stringent hybridization conditions as found in the specification page 15.

One of skill in the art would understand that nucleotide sequences of not less than 50 nucleotides that hybridize under said stringent conditions would have a high degree of identity (at least about 90%), as found in the specification page 15. There is adequate guidance within the specification to allow one of skill in the art to practice the invention and determine which polynucleotides would hybridize under the claimed stringent conditions.

In addition, the Applicants wish to remind the Examiner that although the Examiner states that "there is only a single working example in a genus that contains hundreds of millions of possible promoter constructs", this situation (having only a single working example for the newly amended claims) was created by the sequence restriction required by the Examiner. The currently claimed sequence is only one of

multiple functional embodiments of the invention disclosed within the specification.

With the guidance provided in the present specification, one skilled in the art can readily practice the claimed invention.

Applicants respectfully submit that the claims as amended are now in a condition as amended and request the rejections under 35 U.S.C. § 112 be withdrawn.

Rejections under U.S.C. § 102(b)

Examiner has rejected claims 1-16 under 35 U.S.C. §102(b) as being anticipated by Ishige *et al.* (EP 0754757 A2). Examiner notes "this reference is applied...insofar as they are drawn to include the elected promoter that is 1(c) and also 'a nucleotide sequence that hybridizes under stringent conditions', to the nucleotide sequence of (c)".... Further, the Examiner states that the promoters taught by Ishige *et al.* meet the limitations of claim 1 or 2 because they comprise elements that would hybridize under stringent conditions to the instantly disclosed and claimed promoter of section (c) or is a variant thereof.

Applicants respectfully traverse. The cited reference discloses a promoter which has only 27 of its 98 nucleotides in common with the currently claimed invention including SEQ ID NO.: 65. The Ishige promoter is not capable of hybridizing under stringent conditions (50% formamide, 1M NaCl, 1% SDS at 37°C, and a wash in 0.1X SSC at 60-65°C) with the polynucleotides of claim 2, 8, or 12, including the 413 nucleotides of SEQ ID NO.: 65.

The Ishige et al. reference cited does not show anticipation of the invention of the current application.

> To constitute an anticipation, a reference must disclose within its four corners each and every element of the claimed invention. *Structural Rubber Products Co. v. Park Rubber Co.*, 749 F. 2d 707, 223 U.S.P.Q. 1264 (Fed. Cir. 1984); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 U.S.P.Q. 773 (Fed. Cir. 1985); *Hybritech Inc. v. Monoclonal Antibodies Inc.*, 802 F.2d 1376, 231 U.S.P.Q. 81 (Fed. Cir. 1986).

The promoters of the reference do not fall within the claim limitations, and do not

enable someone to practice the invention. Further the Federal Circuit has held:

> "a reference must enable someone to practice the invention in order to anticipate under § 102(b)" *In Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569, 19 USPQ2d 1241 (Fed. Cir. 1991).

While the position 3-41 nucleotides of the Ishige promoter are 100% homologous to the promoter element disclosed herein and called "AS-1". Ishige didn't teach or recognize that the 3-41 bp subsequence was AS-1, nor did Ishige teach that AS-1 was a 28 bp promoter sub element of the minimal region of the cauliflower mosaic virus 35S promoter. Further, and more importantly, the sequence claimed in the current application is the entire set of promoter elements arranged sequentially as denoted in claim 2(a), or a sequence having at least about 90% sequence identity, as determined by the GAP algorithm, using default parameters, across the full length of SEQ ID NO: 65. Also, the minimal region of Ishige would not be at least about 90% homologous to the entire claimed sequence, nor would it hybridize under stringent conditions to the entire length of the present invention.

However, in an effort to clearly and distinctly point out the claimed invention, the applicant has cancelled claim 1, and amended claim 2, 8 and 12, thereby eliminating a potential overlap in the teachings of Ishige *et al.* with the currently claimed invention. The reference cited by the Examiner does not teach the features of the presently claimed invention and thus does not anticipate. It is respectfully requested that the rejections under 35 U.S.C. § 102 be withdrawn.

Serial No. 09/766,399
Group Art Unit: 1634

CONCLUSION

On the basis of the amendments and remarks, reconsideration of the application and its allowance are respectfully requested.

Respectfully submitted,

Janice L. Rouse
Agent for Applicant
Registration No. 52,183

PIONEER HI-BRED INTERNATIONAL, INC.
Corporate Intellectual Property
7100 N.W. 62nd Avenue
P.O. Box 1000
Johnston, Iowa 50131-1000
Phone: (515) 270-3599
Facsimile: (515) 334-6883